

Hundred and Twenty Dollars (\$920.00) to cover the extension fee as required by 37 C.F.R.

§§1.17(a)(3) and 1.136(a).

**IN THE CLAIMS:**

Cancel claims 27-42.

**REMARKS**

**I. Amendments**

Claims 27-42 have been canceled as a result of the imposition of the restriction requirement. Applicants reserve the right to file a divisional application directed to the subject matter of the canceled claims.

**II. Rejection under 35 U.S.C. § 103(a)**

Claims 1-10 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over US 3,442,686 to Jones ("Jones") in view of US 3,967,728 to Gordon et al. ("Gordon").

The primary reference to Jones is directed to a low permeability packaging film. The film consists of the following layers: an inorganic glassy barrier composition sandwiched between an organic base film and a sealable topcoat (col. 2, lines 38-41). The term "glassy" as used to characterize the intermediate layer is understood to mean a coating which is in the state of a super-cooled liquid or glass (col. 4, lines 30-37). The preferred inorganic materials for the intermediate include non-metallic materials such as oxides of silicon (col. 4, line 34-35).

Admittedly, Jones discloses the laminate of the claimed invention. However, as acknowledged by the Examiner, Jones does not disclose or suggest the use of the laminate as a barrier material against ethylene oxide gas.

*to be for packaging*

*but Jones teaches their laminate  
planner to use packaging material  
of Jones during ethylene oxide  
-2- Sterilization of Gordon  
Gordon only used to show  
ethylene oxide sterilization*

Accordingly, the Examiner relies on the secondary reference to Gordon for the disclosed preference that medical packaging films contain a membrane which is impermeable to sterilizing gases such as ethylene oxide. The Examiner concludes, therefore, that the laminate of Jones must also be impermeable to ethylene oxide gas simply because it is generally described as a low permeability packaging film.

Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness for the following two reasons: (1) the combination of Jones and Gordon are incompatible and their combination would not result in the claimed invention, and (2) the Examiner is relying on an improper "obvious to try" standard of obviousness without a reasonable expectation of success.

*not obvious to try because Jones teaches the instant packaging film are admitted by applicant to protect objects from permeability from gas for liquid.*

1. The combination of Jones and Gordon are incompatible, and their combination would not result in the claimed invention.

The Examiner's attention is directed to Gordon at col. 2, lines 45-50 where it is disclosed that the laminate composite consists of an interior thermoplastic sheet 35, e.g., polyethylene, which is laminated to an outer gas impermeable layer 36, e.g., a metal or aluminum foil.

Thus, Gordon teaches the use of a metal as a barrier material to sterilizing gases such as ethylene oxide (See Figs. 4 and 6). In fact, the term "foil" is defined as meaning "a thin, flexible leaf or sheet of metal". The American Heritage Dictionary, 2<sup>nd</sup> College Edition. There is no suggestion that the barrier layer can be a material other than a metal. As such, Gordon is void of any suggestion or motivation to use a non-metallic layer as a barrier material to ethylene oxide gas.

Therefore, Jones and Gordon are incompatible. The intermediate barrier layer of Jones consists of a glassy, inorganic and non-metallic material. As disclosed by Jones at column 4,

lines 34-37, silicon oxide is an example of a material that can be deposited as a flexible coating in the glassy state. None of the metallic materials disclosed by Gordon satisfy the "glassy" or "glassy state" requirement of Jones. Accordingly, the inorganic, glassy, and non-metallic barrier material of Jones is incompatible with the non-glassy, metallic barrier material of Gordon.

Furthermore, the combination of Jones and Gordon implies the introduction of a metallic barrier layer which is not present in the laminate of the claimed invention. Therefore, the combination of Jones and Gordon would not result in the laminate of the claimed invention.

**2. The Examiner is relying on an improper "obvious to try" standard of obviousness without a reasonable expectation of success.**

The obviousness rejection is based on the disclosure by Gordon that medical packaging materials should be impermeable to sterilizing gases such as ethylene oxide and, therefore, the packaging film of Jones must be impermeable to ethylene oxide. In essence, the Examiner is stating that it would have been "obvious to try" and use the packaging film of Jones as a barrier to ethylene oxide gas.

However, as previously discussed, the intermediate layer of Jones is a glassy, non-metallic material. As acknowledged by the Examiner in the Office Action, Jones is silent with respect to the effectiveness of that laminate as a barrier to ethylene oxide gas. On the other hand, Gordon discloses that metallic materials are effective barriers to ethylene oxide. Therefore, Gordon is also silent with respect to the effectiveness of the laminate of Jones as a barrier to ethylene oxide gas.

Furthermore, the disclosure by Jones of a low permeability membrane does not necessarily mean that the material can be used as a barrier to sterilizing gases. For example, a material which is normally stable at room temperature can quickly degrade or fail when exposed

to sterilizing conditions such as autoclaving or a sterilizing gas. There is no disclosure, either explicit or implicit, that the film of Jones is stable in the presence of a sterilizing gas. The Examiner is improperly attributing a property to Jones' film which is simply not suggested by either Jones or Gordon.

Therefore, the rejection is based on an "obvious to try" standard of obviousness which is improper. The disclosure by Gordon of metallic materials as a barrier to ethylene oxide provides a strong implication that the glassy, non-metallic material of Jones would be ineffective as a barrier material to ethylene oxide. It is only with hindsight, which is also improper, that the Examiner can allege that the claimed invention is obvious in view of the cited prior art.

Accordingly, in view of the failure of the cited art to recognize or appreciate the ability of a silicon oxide-containing laminate to serve as a barrier against ethylene oxide, it would not have been obvious to do (not obvious to try) what Applicants have done. Thus, the direction of Applicants' investigation leading to the claimed invention is clearly not motivated by either Jones or Gordon, either alone or in combination.

For all of the foregoing reasons, withdrawal of the §103 rejection based on the combination of Jones and Gordon is requested.

U.S. Patents 5,942,408; 5,653,090; 3,839,078; and 5,322,161 have been cited by the Examiner as allegedly representing the state of the art. Applicants submit that none of these publications disclose or suggest the claimed invention.

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**CONCLUSION**

Applicants respectfully submit that claims 1-10 are in condition for allowance, which action is earnestly solicited. Authorization is hereby given to charge any fee which may be due in connection with this communication to Deposit Account 23-1703.

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Respectfully submitted,

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